K113422

MAR - 5 2012

510(k) SUMMARY

Prepared for : TERUMO (PHILIPPINES) CORPORATION
124 East Main Avenue, Laguna Technopark,
Binan, Laguna,Philippines

Prepared by : Ma. Cristina Faderagao – Supervisor Regulatory Affairs
Tel. (+63) 49 541 2111
Fax (+63) 49 541 2121

Date prepared : December 21, 2011

Contact Person : Sandi Hartka
Regulatory Affairs Manager
Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Phone#: (410)392-7241
Fax#: (410)398-6079
E-mail: sandi.hartka@terumomedical.com

A. DEVICE NAME

Proprietary Name
TERUMO® SurGuard®3 Safety Needle
TERUMO® SurGuard®3 Hypodermic Syringe with Safety Needle

Classification Name
Hypodermic Single Lumen Needle (880.5570) with antistick

Product Code: 80FMI / 80MEG
Classification: Class II

Common Name
Hypodermic Needle with Safety Sheath or Needle with needle protection device.

B. INTENDED USE

The TERUMO® SurGuard®3 Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TERUMO SurGuard®3 Safety Needle is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

C. DEVICE DESCRIPTION

The TERUMO SurGuard®3 Safety Needle consists of a hypodermic needle with a hinged safety sheath attached to the connector hub with or without an attached hypodermic syringe. This device features a hinged safety sheath attached to the needle hub. The safety sheath contains two locking mechanisms, the sheath tooth-cannula and sheath wings-collar which are simultaneously activated when manually pressed over the needle immediately after use and just prior to disposal to minimize the possibility of sharps injury. The safety sheath is activated with a one-handed operation by pressing the sheath either by finger or thumb, or by surface activation.

The safety sheath has a finger guide area consisting of a circular dent (for thumb activation) and ramp (for finger activation) which gives the user a concrete confirmation that the user's finger is in the appropriate position in performing the activation. The ramp has steps to provide strong grasp when activating the sheath. There are two stoppers located at the end of the circular dent and ramp which assist in preventing the user's finger from going towards the cannula during activation. Another way of activation is by manually pressing the safety sheath over the needle using a firm surface.

The locking mechanisms are positioned within the center and proximal end of the sheath. The hinge feature allows the medical practitioner to flexibly adjust the sheath to its desired position for use. The needle gauge sizes fall within the 18 to 25 gauge range and the needle lengths are 1" to 2".

The TERUMO SurGuard®3 Safety Needle will be individually packaged and sterilized by electron beam as a safety needle only or as a safety needle with attached Terumo syringe. The syringe sizes are 3, 5, and 10cc/ml.

D. SUBSTANTIAL EQUIVALENCE

The TERUMO SurGuard®3 Safety Needle manufactured by Terumo Philippines Corporation is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the following cleared devices:

1. K051865 TERUMO® SURGUARD2 ™ SAFETY NEEDLE with or without syringe manufactured by Terumo (Philippines) Corporation.

The proposed modifications to the device do not raise significant issues of safety and effectiveness.

E. SUMMARY OF TECHNOLOGICAL MODIFICATIONS

The TERUMO SurGuard®2 Safety Needle safety sheath was designed having one locking mechanism thru sheath tooth-cannula. The locking mechanism is located at a designated position within the body of the short or long sheath appropriate for the needle size it is to contain but with the proposed TERUMO SurGuard®3 Safety Needle safety sheath was designed having two locking mechanisms, the sheath tooth-cannula and sheath wings-collar. The locking mechanisms are positioned within the center and proximal end of the sheath.

The differences in the design made to the proposed TERUMO SurGuard®3 Safety Needle in comparison to the cleared TERUMO SurGuard®2 Safety Needle will increase the number of ways to activate the safety feature. The cleared TERUMO SurGuard®2 Safety Needle is activated only by manually pressing the sheath over the needle using a firm surface whereas the proposed TERUMO SurGuard®3 Safety Needle is activated by three methods; by pressing the sheath either by finger or by thumb, or by surface activation.

The TERUMO SurGuard®2 Safety Needle gauge sizes fall within the 18 to 30 gauge range and the needle lengths are 3/8" to 1 ½" whereas the TERUMO SurGuard®3 Safety Needle gauge sizes fall within the 18 to 25 gauge range and the needle lengths are 1" to 2".

The TERUMO SurGuard®2 Safety Needle syringe sizes are 1, 3, 5, and 10cc/ml. The TERUMO SurGuard®3 Safety Needle syringes will be available in 3, 5, and 10cc/ml.

F. Additional Safety Information

Manufacturing controls include visual, functional and sterility tests.

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11137 – Medical Devices – Validation and Routine Control of Radiation Sterilization. The TERUMO SurGuard®3 Safety Needle is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

The TERUMO SurGuard®3 Safety Needle is classified as Externally Communicating Device, Circulating Blood, Limited Duration of Contact (≤24hr.). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO – 10993, "Biological Evaluation of Medical Devices part 1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

G. Conclusion

In summary, the TERUMO SurGuard®3 Safety Needle manufactured by Terumo Philippines Corporation is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the following cleared devices:

1. K051865 TERUMO® Surguard ™ SAFETY NEEDLE with or without syringe manufactured by Terumo (Philippines) Corporation.

The modifications made to the devices covered in K051865 do not raise new issues of safety or effectiveness nor do they affect the intended use/indications for use.

Terumo's statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Sandi Hartka
Manager Regulatory Affairs
Terumo Philippines Corporation
950 Elkton Boulevard
Elkton, Maryland 21921

MAR - 5 2012

Re: K113422
Trade/Device Name: TERUMO® SurGuard®3 Safety Needle and TERUMO® SurGuard Hypodermic Syringe with Safety Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI, MEG
Dated: February 3, 2012
Received: February 6, 2012

Dear Ms. Hartka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113422

Device Name: TERUMO® SurGuard®3 Safety Needle and
TERUMO® SurGuard®3 Hypodermic Syringe with Safety Needle

Indications For Use:

The TERUMO® SurGuard®3 Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TERUMO SurGuard®3 Safety Needle is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/5/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113422